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November 16, 2000

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
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12420 Parklawn Drive
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To Whom It May Concern:

I am a board certified gastroenterologist treating numerous patients with irritable bowel syndrome in Orlando, Florida. I have had the opportunity to use Lotronex ~~and~~ (Alosetron) on numerous patients without any major problems.

I have been somewhat concerned with the amount of lay press that has been generated about this product. I have reviewed some of the reprints on some of the adverse reactions which I have not seen in my own patients. I have not run across ischemic bowel disease, and I have used this product in young as well as older women with diarrhea predominant IBS. This medicine has been a great breakthrough in the treatment of irritable bowel syndrome with diarrhea predominance allowing these ladies to gain quality of life, being able to be unchained from a bathroom facility and proceed on with a daily activity.

I feel that this medicine has a place in the armamentarium for irritable bowel syndrome and should be used in the patients as pointed out in the package insert, and if used carefully and cautiously should not have very many side-effects. As you know, constipation is a common side-effects and I have experienced that with several patients, but they have been able to work through this with usually increasing water and occasional laxative use. I have not had to discontinue patients because of constipation nor have I seen ischemic bowel disease or adverse outcomes of this severe nature. I do feel that it is likely a selection of the right patient which will allow this medicine to be used properly and remain in our armamentarium to help treat the very serious condition of irritable bowel with diarrhea predominance.

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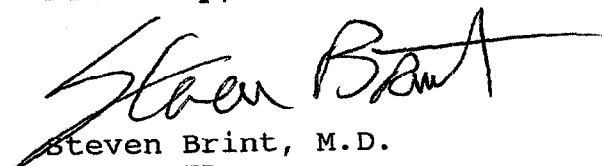
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Page Two

I hope after the review by your department this medicine is allowed to stay in our armamentarium, and I do not hesitate at all to prescribe it as long as it is in the appropriate population which I think is outlined very well in the package insert.

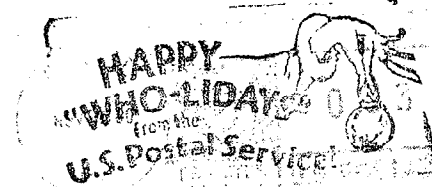
Thank you again for taking the time to review the thoughts of a practicing gastroenterologist.

Sincerely,



Steven Brint, M.D.
Ocoee, FL

SB/jr



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